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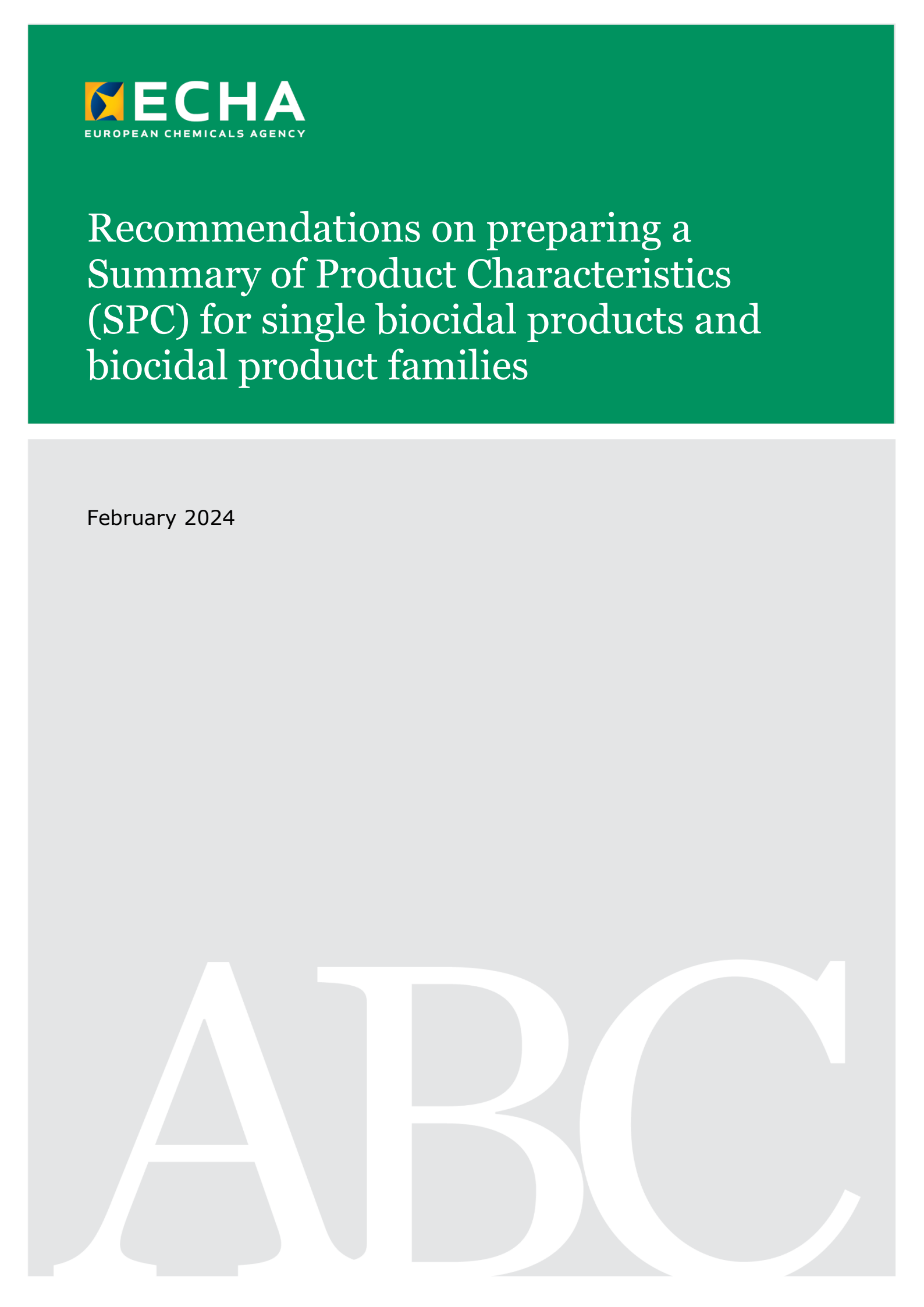
Recommendations on preparing a Summary of Product Characteristics (SPC) for single biocidal products and biocidal product families

February 2024



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Recommendation on preparing a Summary of product Characteristics (SPC) for single biocidal products and biocidal product families

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[1] Applicability of the documents referenced in the recommendation is to be checked from the respective documents.

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Preface

An authorisation of a biocidal product – be it a single biocidal product or a biocidal product family – includes the so-called Summary of Product Characteristics (SPC) as laid down in Article 22 of the Biocidal Products Regulation (BPR, EU No 528/2012). Consequently, the SPC is an important result of the authorisation process, not only for the authorisation holder but also for Competent Authorities in the Member States (MSCAs), including enforcement authorities. The quality of the SPC is therefore of utmost importance with respect to its content, but also related to aspects like clarity and readability.

The document serves as a compilation of various agreements made in the Coordination Group, Biocides Competent Authority meetings and Biocidal Products Committee meetings related to the content of the SPC and aims to help the reader in preparing a clear and comprehensible SPC, which follows the legal obligations.

The content of the recommendation is applicable for simplified, national and Union authorisation. In relevant parts it is indicated if the instruction concerns only one type of authorisation.

The document follows the structure of an SPC for a single biocidal product, as detailed in the Competent Authority CA document[2], and it is applicable to biocidal product families as well. The order of the sections of the document does not necessarily match the structure of the dedicated configuration of SPC in IUCLID, but corresponds to the SPC report generated by IUCLID.

[2] CA-Sept14-Doc.5.4 - Final - SPC template reviewed

List of Abbreviations

Abbreviation	Explanation
AH	Authorisation holder
AS	Active substance
AVK	Anti-vitamin K
BPC	Biocidal Products Committee
BP	Biocidal product
BPF	Biocidal product family
BPR	Biocidal product regulation (EU) No 528/2012
CA	Competent authority
CG	Coordination group
cMSs	Concerned Member States
H-statement	Hazard statement (from the CLP Regulation)
MR	Mutual recognition
MS	Member State
NA	National authorisation
P-statement	Precautionary statement (from the CLP Regulation)
PT	Product type
rMS	Reference Member State
RMM	Risk mitigation measure
RTU	Ready to use
SoC	Substance of Concern
SPC	Summary of Product Characteristics
UA	Union authorisation

1. Administrative information

1.1 Trade name(s) of the product (BP) / Family name (BPF)

Trade name(s)	

Instructions and agreements:

- In case the product would have more than one name, all names can be provided in this field (*CA-Sept14-Doc.5.4 – Final*).
- For Union authorisation (UA) trade names should not be translated, but rather all trade names in all Member states should be included in the English (master) SPC and also in the SPCs translations.
- For national authorisation (NA) this field in the SPC is MS-specific, so it will only include the name(s) authorised in that MS (*CA-May15-Doc.4.4 – Final.rev4*).

1.2 Product type(s) (BPF)

Product type(s)	

Instructions and agreements:

- In case the family would belong to more than one product type (PT), all PTs can be provided in this field (*CA-May15-Doc.4.6.a – Final*).

1.2 Authorisation holder (BP) / 1.3 Authorisation holder (BPF)

Name and address of the authorisation holder	**Name**	
	Address	
Authorisation number		
Suffixes to the authorisation number linked to trade names		
R4BP asset reference number		
Date of the authorisation		
Expiry date of the authorisation		

Instructions and agreements:

- Name and address of the authorisation holder (AH) are information imported from R4BP and should not be filled out when preparing the SPC in IUCLID. Authorisation number, date of the authorisation, as well as expiry date of the authorisation, are set by the Member State granting the national authorisation or by the Commission when the authorisation is granted for Union authorisation, so these fields should not be filled in when preparing an SPC in IUCLID.

1.3 Manufacturer(s) of the product (BP) / 1.4. Manufacturer(s) of the biocidal products (BPF)

Name of manufacturer	
Address of manufacturer	
Location of manufacturing sites	

Instructions and agreements:

- Only sites where the manufacturing processes leading to the final biocidal product take place (except sites that perform filling operations) or, where they are different, those which allocate the production batch numbers referred to in Article 65(2)(d), should be listed in the SPC. Upon request from a Competent Authority (CA), for enforcement purposes for instance, the AH shall without delay provide information on the different sites involved in the whole manufacturing process, including contract manufacturers (*CA-May15-Doc.4.4 – Final.rev4)*.
- Contract manufacturers carrying out filling operations are subject to the relevant obligations referred to in Article 65(2) of the BPR and where relevant, to national legislation regarding the registration or authorisation of manufacturers of biocidal products (*CA-May15-Doc.4.4 – Final.rev4)*.
- Biocidal product family (BPF): All the manufacturers and manufacturing sites for any individual products within the family should be listed (*CA-May15-Doc.4.6.a – Final*).
- The location of the manufacturing site(s) for the manufacturer(s) of the biocidal product (s) (BP(s)) has to be mentioned in the published SPC, i.e., it cannot be regarded as confidential in accordance with Article 66 of the BPR (*CA-May15-Doc.4.4 – Final.rev4*).
- NA: The draft SPC provided by the reference Member State (rMS) to the concerned Member States (cMSs) in case of mutual recognition (MR) in parallel (or the SPC authorised in case of MR in sequence) should list all manufacturers of the product, so this would cover the manufacturers in all the MSs (*CA-May15-Doc.4.4 – Final.rev4*).
- NA MR procedures: the authorisation in cMSs shall be subject to the same terms and conditions as in the rMS. Once the cMS has granted the national authorisation, the AH can notify an administrative change in order to add a new manufacturer in that MS, provided that the product composition and the manufacturing process remain unchanged. It has to be noted that this administrative change would not have any impact regarding the renewal procedure in accordance with Regulation 492/2014 (*CA-May15-Doc.4.4 – Final.rev4)*.

1.4 Manufacturer(s) of the active substance(s) (BP) / 1.5. (BPF) Manufacturer(s) of the active substance(s)

Active substance	
Name of manufacturer	
Address of manufacturer	
Location of manufacturing sites	

Instructions and agreements:

- The location of the manufacturing site(s) for the manufacturer(s) of the active substance(s) (AS(s)) has to be mentioned in the published SPC, i.e., it cannot be regarded as confidential in accordance with Article 66 of the BPR (*CA-May15-Doc.4.4 – Final.rev4*).

2. Product composition and formulation

2.1 Qualitative and quantitative information on the composition of the product (BP)/of the family (BPF)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
		Active substance			
		Non-active substance			

Instructions and agreements:

- Content of AS should always be given as % w/w (not e.g., v/v). For details on expressing the content of the AS please refer to Q10 in *CA-May15-Doc.4.4 – Final.rev4.*
- Non-active substance(s) knowledge of which is essential for proper use of the product should be included. In the draft SPC in the application the applicant shall also indicate the exact function (e.g., solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of the non-active substance (*CA-Sept14-Doc.5.4 – Final, CA-May15-Doc.4.6.a - Final*).
- Note that functions others as active substance will appear in the SPC report as ""non-active substance"[3].
- The question of which non-active substances should be considered as, knowledge of which is essential for the proper use of the product, should be addressed on a case-by-case basis according to the outcome of the risk assessment, which may depend on the properties and function of the non-active substances within the biocidal product. Non-active substances considered as SoCs should be listed in all cases (*CA-May15-Doc.4.4 – Final.rev4, CG-44_e-c Soc and EUH labelling_Final*).
- Express the content of non-active substance as the content of the non-active substance including any additives necessary to preserve its stability and any impurity derived from the process used (*CA-May15-Doc.4.4 – Final.rev4, BPC-31 agenda item 8.4 and BPC-33 agenda item 8.1*).
- For the following active substances: i) active chlorine released from sodium hypochlorite; ii) active chlorine released from calcium hypochlorite iii) active chlorine released from hypochlorous acid; and iv) active chlorine released from chlorine:
    - the content of available active chlorine is presented under the common name "Active chlorine released from [name releaser]", where the function is "Active substance" and neither CAS, nor EC number is indicated and
    - the content of the releaser (expressed as technical material) is presented where the common name is the name of the releaser; the function is "Releaser" and the concerned CAS and EC numbers – if available – are indicated. (*BPC-40 agenda item 8.3*)[4].

[3] Agreement from BPC-23 agenda item 8.2 and BPC-31 agenda item 8.4 is implemented in the SPC in IUCLID directly

[4] The SPC editor has to be amended to make it possible to list "Releaser" under the heading "Function" and have it visible for dissemination purposes. Before this change is implemented to the SPC Editor, the "Function" in the disseminated document can only be "Non-active substance".

2.2 Type of formulation (BP) / 2.2. Type(s) of formulation (BPF)

Instructions and agreements:

- In case the family would have more than one formulation type, all types can be provided in this field (*CA-May15-Doc.4.6.a – Final*).
- In exceptional cases there might be more than one formulation type for single biocidal product *(BPC-43 agenda item 8.3 and 8.10*).

3. Hazard and precautionary statements (BP) / 3. Hazard and precautionary statement of the meta SPC (BPF)

Hazard statements	
Precautionary statements	

Instructions and agreements:

- According to Regulation (EC) 1272/2008 This section shall only include P-statements triggered by the CLP legislation. List all P-statements triggered by H-statements (*CA-May13-Doc.5.4, CA-Sept14-Doc.5.4 – Final, CA-May15-Doc.4.4 – Final.rev4, CA-May15-Doc.4.6.a – Final, BPC-29 agenda item 8.3*).
- A P-statement that has been proven unnecessary in the risk assessment because of the intended use of the product should be left out of the SPC and of the label (*CA-May13-Doc.5.4, CA-May15-Doc.4.4 – Final.rev4, CA-May15-Doc.4.6.a – Final, CA-Sept14-Doc.5.4 – Final*).
- Every P-statement triggered by the CLP Regulation should be always included in section 3 of the SPC, unless it is proven unnecessary. When the same sentence is triggered at the same time by the CLP Regulation and by the risk assessment, then a repetition of this sentence is possible both as a P-statement in section 3 and as a risk mitigation measure (RMM) in section 5 (*CG-51_e-c Inclusion of P-statements in SPC_Final*).
- In case sentence P101 "If medical advice is needed, have product container or label at hand", P102 "Keep out of reach of children" or P103 "Read carefully and follow all instructions" is triggered by CLP Regulation (H-Statement) it also needs to be stated in section 3 of the SPC (*CG-51_e-c Inclusion of P-statements in SPC_Final*).
- P-statements should be completed (*BPC-29 agenda item 8.3*), e.g., P231 "Handle and store contents …".
- Hazard statements should be interpreted broadly to encompass also "supplementary hazard statements" such as the EUH statements referred to in the CLP Regulation (*CA-May15-Doc.4.4 – Final.rev4*).
- Only those hazard statements should be listed which are necessary for labelling purposes, e.g., in case a product is classified as both H314 and H318, then H318 is not needed in the SPC, as it is already covered by H314 *(BPC-40 agenda item 8.4).*
- For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work) (*CA-Sept14-Doc.5.4 – Final CA-May15-Doc.4.6.a - Final*).

4. Authorised use(s) (BP) / 4. Authorised uses of the meta SPC (BPF)

General instructions and agreements concerning all sections below:

- All instructions for use, RMMs and other directions for use that are valid for all authorised uses of a single biocidal product (*CA-Sept14-Doc.5.4 – Final*) or valid for all authorised uses within the meta SPC (*CA-May15-Doc.4.6.a – Final*) should not be included under this section, but under section 5.
- Please consult the agreed list of frequently used sentences in the SPC and their translations and use them, if appropriate (*available at https://www.echa.europa.eu/support/dossier-submission-tools/spc-editor).*
- Please make sure to explain all abbreviations used when they appear the first time (e.g. HDPE = high-density polyethylene, GMP = Good Manufacturing Practice etc.).
- The International System of Units should be used.
- Please give instructions in active rather than passive voice.
- Please try to keep the SPC clear and comprehensible and avoid repetition of the same information in different fields.
- PT14 anticoagulant rodenticides: Please use the agreed harmonised sentences for SPC AVKs (*CA-March23-Doc.4.15*).

4.1 Use description

Table 1. Use # 1 – name of the use

Product Type	
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	
Field(s) of use	
Application method(s)	
Application rate(s) and frequency	
Category(ies) of users	
Pack sizes and packaging material	

Instructions and agreements:

- Add as many "Authorised uses" sections as needed in the dedicated configuration of SPC in IUCLID. The SPC of a single biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence (*CA-Sept14-Doc.5.4 – Final, CA-May15-Doc.4.6.a - Final*).
- Name of the use ("Title for use" in the dedicated configuration of SPC in IUCLID) should provide a short or synoptic description of the authorised use, which is further detailed in the associated table below the name of the use. See some examples below for different PTs:
  - For PT 14: Mice – non-professionals – indoor; Rats – professional users – sewers – large blocks,
  - For PT 8: Wood staining fungi – professional users – spraying – outdoor,
  - For PT 19: Repellent – (adult) mosquitos – general public (above 12 years) – spraying

– outdoor.

The terms chosen for the description of the authorised use should facilitate the comprehension by final users and inspectors. This is of particular relevance for SPCs of single biocidal products with a number of authorised uses for which separate product labels can be placed on the market (*CA-May15-Doc.4.4 – Final.rev4).*

- The field "where relevant, an exact description of the authorised use" is intended to provide a more specific description of the use for those PTs where different uses are referred to within the PT description of Annex V to the BPR (e.g., repellent or attractant in PT 19; disinfectant of drinking water for humans or for animals in PT 5; insecticide or acaricide in PT 18, etc.). This field would be left empty for other PTs (*CA-May15-Doc.4.4 – Final.rev4*).
- Please note under the field "Application method(s)" the following fields "Method", "Detailed description of the method", "Application rate" and "Number and timing of applications" are included. Unnecessary repetition should be avoided in these sections.
- In addition to the application rate, contact time should be given, where relevant. For determining the use concentration and contact time for PT 1-5 disinfectants with a variety of different test concentrations and contact times for the various groups of target organisms please consult *CG-55_e-c Concentration, contact time for various groups of target organisms_vf*. For RTU products the field "Dilution (%)" should be left empty.
- NA MR procedures: Where a target organism cannot be authorised by the rMS on the grounds referred to in Article 37(1)(e) of the BPR, such target organism should be included in the draft SPC proposed by the rMS (in EN) and be also reflected in the agreed SPC. The specific situation in the rMS should be clearly flagged in the agreed SPC (e.g., by adding a footnote "The target organism (or use) cannot be authorised in the rMS due to ….."). However, for consistency and in order to avoid any misunderstandings by the readers of the final SPC issued by the rMS, section 4 should list the authorised target organisms only (*CA-May15-Doc.4.4 – Final.rev4*).
- PT14 Pack sizes and packaging material: Please consult the Harmonised approach on how to report the packaging size and packaging materials of PT14 products in the SPC (*CG-34-2019-18 AP 14.1.2*).
- For biocidal products with carrier material (types "C"): Please include a brief description of the carrier material (CA-Nov16-Doc.4.3 – Final. Rev 2.).

4.1.1 Use-specific instructions for use

Instructions and agreements: In case there are no use specific instructions, include reference to section 5.1.

Note: Sections 4.1.1, 4.1.2, 4.1.3, 4.1.4 and 4.1.5 are grouped under "Use-specific directions for use" in the dedicated configuration of SPC in IUCLID.

4.1.2 Use-specific risk mitigation measures

Instructions and agreements: In case there are no use specific RMMs, include reference to section 5.2..

- RMMs resulting from the risk assessment should be referred to in here, where they are use-specific, or under heading 5.2 where they are applicable to any of the authorised uses (*CA-May15-Doc.4.4 – Final.rev4*).

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Instructions and agreements: In case there are no use specific particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment, include reference to section 5.3.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

Instructions and agreements: In case there are no use specific instructions for safe disposal of the product and its packaging, include reference to section 5.4.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Instructions and agreements: In case there are no use specific conditions of storage and shelf-life of the product under normal conditions of storage, include reference to section 5.5.

5. General directions for use

General instructions and agreements concerning all sections below:

- Instructions for use, RMMs and other directions for use under this section are valid for all authorised uses of a single biocidal product (*CA-Sept14-Doc.5.4 – Final*) or valid for all authorised uses within the meta SPC (CA-May15-Doc.4.6.a – Final).
- PT14 anticoagulant rodenticides: Please use the agreed harmonised sentences for SPC AVKs (*CA-March23-Doc.4.15*).

5.1 Instructions for use

Instructions and agreements:

- Describe the necessary instructions relevant for all uses in single biocidal product or all uses under meta SPC in biocidal product family like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance (*CA-Sept14-Doc.5.4 – Final, CA-May15-Doc.4.6.a - Final)*.
- For non-professional / general public uses, the sentence P103 "Read carefully and follow all instructions." should be adapted to "Comply with the instructions for use" and included in this section (*CG-51_e-c Inclusion of P-statements in SPC_Final*).

5.2 Risk mitigation measures

Instructions and agreements:

- BP: Instructions for use, RMMs and other directions for use under this section are valid for all authorised uses of a single biocidal product (*CA-Sept14-Doc.5.4 – Final*).
- BPF: Instructions for use, RMMs and other directions for use under this section are valid for all authorised uses within the meta SPC (*CA-May15-Doc.4.6.a – Final*).
- Do not include RMMs like "The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management", as these are not regarded as use specific RMMs but obligations for the authorisation holder related to resistance management. It is a horizontal policy issue that needs to be further analysed, before such sentence can be included in the SPC or in the terms and conditions of the authorisation. (*BPC-35 agenda item 8.3*).

5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Instructions and agreements:

- For non-professional / general public uses the spirit of the sentence P101 "If medical advice is needed, have product container or label at hand" could be adapted and included into this section (*CG-51_e-c Inclusion of P-statements in the SPC_Final*).
- For first aid instructions please consult the "Guidance for harmonisation of first aid instructions

in the authorisation of biocidal products" (*CG-51_e-c Guidance for first aid instructions_vf*).

5.4 Instructions for safe disposal of the product and its packaging

Instructions and agreements.

5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Instructions and agreements:

- For non-professional / general public uses the sentence P102 "Keep out of reach of children" should be adapted to "Keep out of reach of children and non-target animals/pets" and included in this section (*CG-51_e-c Inclusion of P-statements in the SPC_Final*).

6. Other information

Instructions and agreements:

- PT14 anticoagulant rodenticides: Please use the agreed harmonised sentences for SPC AVKs (*CA-March23-Doc.4.15*).
- For biocidal products with carrier material (types "A" or "B"): Please include a brief description of the carrier material (CA-Nov16-Doc.4.3 – Final.Rev 2.).

7. References

Documents agreed at CA meetings:

- CA-May13-Doc.5.4 - Final.rev1 - Classification and labelling of biocidal products
- CA-Sept14-Doc.5.4 - Final - SPC template reviewed
- CA-May15-Doc.4.4 – Final.rev4 - Q&A on SPC content
- CA-May15-Doc.4.6.a - Final - Updated SPC template for BPF
- CA-March23-Doc.4.15 - Harmonised sentences SPC AVKs
- CA-Nov16-Doc.4.3 – Final. Rev 2. - Handling "carriers" in the authorisation of biocidal products.

Available at: https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a

Path: /CircaBC/SANTE/BPR - Public/Library/documents_finalised

Documents agreed at CG meetings:

- CG-34-2019-18 AP 14.1.2 Harm for reporting_packaging size and material PT14_vf
- CG-44_e-c SoC and EUH labelling_FinalCG-51_e-c Guidance for first aid instructions_vf
- CG-51_e-c Inclusion of P-statements in SPC_Final
- CG-55_e-c Concentration, contact time for various groups of target organisms_vf
- CG-54_e-c Use of the term as required for the application frequency_vf

Available at: https://webgate.ec.europa.eu/s-circabc/w/browse/89efe476-1017-46af-8a31-6ad845f79d04

Path: /CircaBC/echa/Biocides CoordinationGroup_public/Library/General agreements

Other documents:

- Frequently used sentences in the SPC and translations

Available at: https://www.echa.europa.eu/support/dossier-submission-tools/spc-editor

- SPC AVKs translations

Available at: https://www.echa.europa.eu/support/dossier-submission-tools/spc-editor)

- BPC minutes

Available at: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/meetings-of-the-biocidal-products-committee/2022

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